DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 6, 2014

Medtronic, Inc.
% Ms. Rishi Sinha
Principal Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, FL 32259

Re: K141704
Trade/Device Name: Novashield Injectable Nasal Packing And Stent
Regulation Number: 21 CFR 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: June 24, 2014
Received: June 25, 2014

Dear Ms. Sinha,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Indications for Use:

NovaShield™ is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to:

- Separate tissue or structures compromised by surgical trauma;
- Separate and prevent adhesions between mucosal surfaces in the nasal cavity;
- Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation
- Act as an adjunct to aid in the natural healing process

NovaShield™ is indicated for use as a nasal packing to treat epistaxis.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter:	Medtronic® Xomed® 6743 Southpoint Drive North Jacksonville, Florida 32216
Contact Person:	Rishi Sinha Principal Regulatory Affairs Specialist Phone: (269) 903-4373 Fax: (269) 353-5924 E-mail: rishi.k.sinha@medtronic.com
Date Summary Prepared:	September 3rd, 2014
Device Trade Name:	NovaShield™ Injectable Nasal Packing and Stent
Common Name:	Intranasal Packing and Stent, Intranasal Splint
Classification Name:	Intranasal Stent
Predicate Device:	K120958 – PosiSep® and PosiSep® X Hemostat Dressings K113585 – Nasal/Epistaxis Pack
Device Description:	NovaShield™ is a single use, injectable nasal packing and stent for use following sinus surgery to prevent adhesions, control mild bleeding and provide a level of antibacterial effectiveness. NovaShield™ is composed of formulated chitosan and cellulose ingredients in a fully mixed and hydrated gel form provided in a prefilled delivery system. The syringe delivery system conveys the gel to the patient via an accordion cannula that can be manipulated to assist with the gel application. NovaShield™ is eliminated via hydrolysis and gentle irrigation using saline or water in approximately 7-14 days. NovaShield™ is intended for use in patients undergoing sinus surgery as a space occupying packing to separate tissue or structures compromised by surgical trauma. NovaShield™ is designed to separate tissue and prevent adhesions between mucosal surfaces during healing in the nasal cavity and for the treatment of mild bleeding from topical surgical wounds and nosebleeds. NovaShield™ may be used for the local management of wounds that are prone to bleeding such as wounds that have been surgically or mechanically debrided and for the management of surgical or traumatic wounds which have been left to heal by secondary intention. NovaShield™ also has been shown in laboratory studies to provide a level of antibacterial activity.
Indications for Use:	NovaShield™ is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to: • Separate tissue or structures compromised by surgical trauma. • Separate and prevent adhesions between mucosal surfaces in the nasal cavity. • Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation. • Act as an adjunct to aid in the natural healing process. NovaShield™ is indicated for use as a nasal packing to treat epistaxis.

Substantial Equivalence: NovaShield™ is substantially equivalent to the following devices:

- Hemostasis® PosiSep and PosiSep X Hemostat Dressings (K120958)
- CogENT® Nasal/Epistaxis Pack (K113585)

Performance Testing: Performance testing was conducted on the NovaShield™ device to ensure the product meets all of the intended design inputs. Bench and animal testing conducted on NovaShield™ demonstrates the product will perform as intended.

Antibacterial Information: The antibacterial effectiveness of NovaShield™ was tested against the following bacterial strains. The table below outlines the timeframe in which NovaShield™ demonstrated antibacterial activity to the tested bacterial strain. Note: *In vitro efficacy is not correlated to clinical effectiveness.*

Bacterial Strain	ATCC #	24 hours	3 days	7 days
Pseudomonas aeruginosa	9027	✓	✓	✓
Staphylococcus aureus	25923		✓	✓
Staphylococcus epidermidis	12228	✓	✓	✓
Echerichia coli	25922			✓
Citrobacter freundii	8090	✓	✓	✓
Enterobacter aerogenes	13048			✓
Klebsiella pneumonia	4352	✓	✓	✓
Proteus mirabilis	4630		✓	✓
Serratia marcescens	13880			✓
Haemophilus influenzae	53782	✓	✓	✓
Moraxella catarrhalis	8193		✓	✓
Staphylococcus aureus(MRSA)	33591			✓
Staphylococcus saprophyticus	15305	✓	✓	✓
Micrococcus luteus	49732		✓	✓
Streptococcus mutans	25175		✓	✓
Streptococcus pneumoniae	10015			✓
Corynebacterium diphtheriae	296		✓	
Corynebacterium tuberculostearicum	35693		✓	